



# MISSOURI BOARD OF PHARMACY

2007 ANNUAL REPORT July 1, 2006 through June 30, 2007



MATT BLUNT, GOVERNOR STATE OF MISSOURI

DOUGLAS M. OMMEN, DIRECTOR
DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND
PROFESSIONAL REGISTRATION

DAVID T. BROEKER, DIRECTOR DIVISION OF PROFESSIONAL REGISTRATION





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# DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION

# DIVISION OF PROFESSIONAL REGISTRATION BOARD OF PHARMACY MEMBERS AND STAFF

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Web Site http://www.pr.mo.gov/pharmacists.asp Email: pharmacy@pr.mo.gov

#### **BOARD MEMBERS**

Douglas R. Lang, R. Ph., President
Pamela L. Marshall, R.Ph., Vice President
Gary F. Sobocinski, R. Ph. Member
Elaina M. Wolzak, R. Ph., Member
Melissa A. Graham, R. Ph., Member
James D. Riddle, R.Ph., Member (appointed 4/26/07)
Anita K. Parran, Public Member
Barbara A. Bilek, R.Ph., Member
(replaced Douglas Lang 6/7/07)

#### **BOARD INSPECTORS**

Thomas Glenski, R. Ph., Chief Inspector Michael Kidd, R. Ph., Inspector Robert "Bud" Alexander, R. Ph., Inspector Frank VanFleet, R.Ph., Inspector Barbara A. Wood, R. Ph., Inspector Sidney "Sid" Werges, R. Ph., Inspector John Heavin, R.Ph., Inspector (deceased 11/06) vacant Inspector position

# **EXECUTIVE DIRECTOR**

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Debra C. Ringgenberg, R.Ph.

## **OFFICE STAFF**

Tammy Siebert Regina Divine Don Walker Laura Payton Lea Tuttle Executive Assistant
Pharmacist and Intern Coordinator
Compliance Coordinator
Pharmacy Technician Coordinator

**Pharmacy and Drug Distributor Coordinator** 

# ORGANIZATION AND DESCRIPTION OF THE BOARD OF PHARMACY

# **MISSION**

The Board's mission is to promote, preserve and protect the public health, safety and welfare by assuring the provision of quality pharmaceutical care to the citizens of Missouri, through the regulation of the practice of pharmacy.

# **ORGANIZATION**

The Missouri Board of Pharmacy is an agency within the Division of Professional Registration, Department of Insurance, Financial Institutions and Professional Registration. The Board was created by House Bill No. 87 of the General Assembly of 1909. The Board consists of seven (7) persons, one who is a public member and six (6) who are licensed pharmacists actively engaged in the practice of pharmacy. At least one of these members must be a person who provides, on a full-time basis, pharmaceutical services to a hospital, skilled nursing facility  $\mathbf{or}$ intermediate care facility. Board Members are appointed by the Governor and hold office for (5) years from the date of their appointment and until their successors have been appointed and Board Members appointed by the Governor are subject to approval of the Senate. Annually, the Board shall organize by the election of a president, and a vice president, each of whom serves for one year. The Board maintains a record of all of its proceedings through the maintenance of minutes for both its open and closed session meetings, pursuant to provisions in Chapter 610 and 620.

The Board appoints five members to an Advisory Committee for Drug Distributors. This committee advises and makes recommendations to the Board concerning any rule changes proposed involving the drug distributor licensing program. A list of the current members of the committee is available at the Board of Pharmacy office.

The Board is an active member of the National Association of Boards of Pharmacy, and a member of District 6 in NABP.

# **AUTHORITY AND FUNCTION**

Sections 338.035, 338.140, 338.280 and 338.350 RSMo 2000 provide the Board authority to adopt rules and regulations for the application and enforcement of Chapter 338, RSMo. The Board has superintending control over the practice of pharmacy in the State of Missouri and its primary duties consist of:

- 1. Examining and licensing of applicants;
- 2. Accrediting of pharmacy colleges;
- 3. Renewing biennially, the licenses of qualified pharmacists, pharmacies, drug distributors, and renewing annually, the licenses of intern pharmacists;
- 4. Registering and renewing pharmacy technicians annually.
- 5. Investigation of complaints involving any licensee or registrant received including public complaints, information from other state and/or federal agencies, or violations discovered during routine inspections of pharmacy and drug distributor operations;
- 6. Suspending, revoking, or placing on probation the license of any pharmacist, pharmacy, drug distributor, or intern pharmacist found to be in violation of Chapter 338, RSMo;
- 7. Placing on conditional registration and maintaining the Technician Employment Disqualification List for pharmacy technicians found to be in violation of Chapter 338, RSMo;
- 8. Inspection of pharmacies and drug distributors; and
- 9. Approval of preceptors and intern training pharmacies.

Several publications are available through the Board of Pharmacy, including the Annual Report and the Board of Pharmacy quarterly Newsletter.

DEBRA C. RINGGENBERG, R.PH EXECUTIVE DIRECTOR

# **BOARD INITIATIVES**

At an annual retreat in March, the Board identified pharmacy issues and reviewed statutes and regulations. They also reviewed board office activities, statistics and identified areas which need improvement or change. Topics discussed included:

## Legislation:

- A. Model Practice Act language & regulatory framework for the provision of Medication Therapy Management (MTM) services
- B. Where is the point of practice of pharmacy and how to design an appropriate regulatory framework
- C. Reciprocity process for licensure
- D. Litigation cost containment strategies, fining authority.
- E. Remote pharmacy services

# **Regulation:**

- F. Appropriate time frame to transfer a prescription to another providing pharmacy
- G. Separate regulation to delineate and define drug utilization review
- H. Review of the provision of pharmacy care and medication/prescription orders for residents in long term care facilities
- I. Pill splitting rules allow opt out for any pharmacists or patient.
- J. Financial management of Board fund
- K. Regulation requiring a log of return to stock items
- L. Storage of pharmacy records offsite
- M. 20 CSR 2220-2.016 Pharmacy Operating Procedures during Declared Disasters
- N. 20 CSR 2220-2.140 Prescription Services by Pharmacists/Pharmacies for Residents in Long Term Care Facilities
- O. Delivery of drugs to the patient or patient's agent
- P. Fingerprinting interns
- Q. Delinquent CE rule amendment
- R. New rules for pharmacist administration of vaccinations and medication therapeutic services
- S. Well-being program

# Legislation and Regulation:

- T. Definition of "professional judgment"
- U. Pharmacist moving away from product assembly and into patient centric services
- V. Proposed changes to electronic records (imaging) and record keeping requirements
- W. Drug distributor laws and regulations
- X. Laws and drug distributor regulations regarding counterfeit drugs

#### **Procedure:**

- Y. Electronic distribution of Board of Pharmacy newsletters
- Z. Discipline of pharmacists versus technicians
- AA. Performance of legal counsel in management of case load
- BB. Board member succession planning
- CC. Legislative plan
- DD. Board meeting dates 2008
- EE. Medication error reporting to national database
- FF. Logo shirts for Board members and staff
- GG. NABP Wholesale Distributor VAWD Program Discussion

# **\$\$ FINANCIAL INFORMATION \$\$**

The Missouri Board of Pharmacy's appropriation for fiscal year ending June 30, 2007 was as follows:

| Personal Service             | \$<br>886,105   |
|------------------------------|-----------------|
| <b>Expense and Equipment</b> | \$<br>528,938   |
| <b>Criminal History Fund</b> | \$<br>150,000 E |
| Transfers*                   | \$<br>559 936   |

## \*Transfers include:

- Rent
- Professional Registration
- DED/MIS
- Licensee Refunds
- Attorney General
- Administrative Hearing Commission
- Office of Administration Allocated Expenses

# **BOARD MEETING INFORMATION**

During the fiscal year ending June 30, 2007, the Board met in regular session a total of 20 days, held two conference call meetings.



# INSPECTION INFORMATION

During the fiscal year ending June 30, 2007, the board inspectors conducted a total of 926 regular inspections of pharmacies and drug distributors throughout the state. This total does not include additional trips to a pharmacy or drug distributor for follow-up inspections or investigations.

# **GOLD CERTIFICATES ISSUED**

The following individuals received Gold Certificates during 2007, which are signed by the Governor of the State of Missouri, as well as by the Board Members and the Executive Director. The certificate represents fifty (50) years of active service as a Missouri pharmacist.

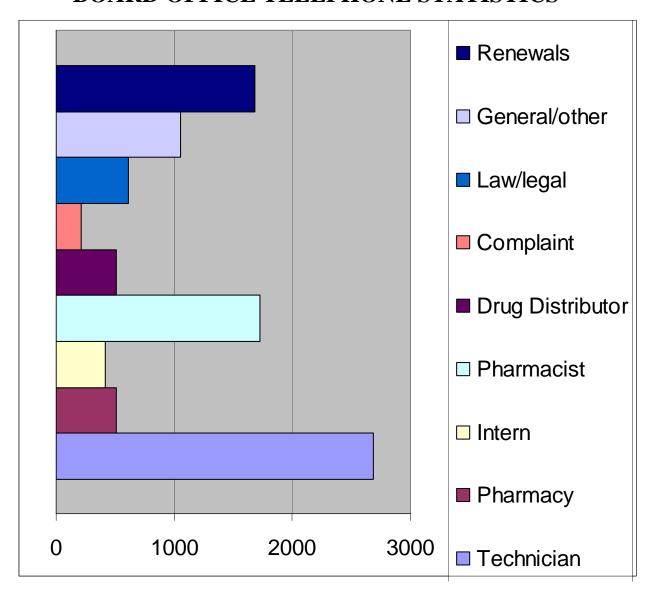
| Behm, Frederick V.       | Affton       | MO |
|--------------------------|--------------|----|
| Boss, Jerold W.          | St. Louis    | MO |
| Boss, Jerold W.          | Webb City    | MO |
| Bruner, Lee R.           | Springfield  | MO |
| Burgess, Donald D.       | O'Fallon     | MO |
| Dominguez, Conchita      | St. Louis    | MO |
| Goldenhersh, Edward L.   | Los Angeles  | CA |
| Heller, Stanley J.       | Chesterfield | MO |
| Kaemmerer, Leonard J.    | Florissant   | MO |
| Kintz, Victor J.         | St. Louis    | MO |
| Nessing, Pierre A.       | Florissant   | MO |
| Ollanik, Jordan          | Tucson       | AZ |
| Schneider, Richard P.    | St. Charles  | MO |
| Schneiderman, Stanley L. | Chesterfield | MO |
| Shark, J.                | Florissant   | MO |
| Sims, George E.          | Kansas City  | KS |
| Smith, William M.        | San Antonio  | TX |
| Tockstein, Alvin O.      | Belleville   | IL |
| Vanbreusegen, Frank E.   | St. Louis    | MO |
| Vetter, William R.       | St. Louis    | MO |
| Wahlbrink, Raymond E.    | Louisville   | KY |
| Walters, Robert E.       | St. Peters   | MO |
| Wiegand, Daniel R.       | Edwardsville | IL |
| Winch, Everett W.        | Independence | MO |
|                          |              |    |



# OTHER BOARD INFORMATION

During the fiscal year 2007 Board of Pharmacy office staff received and responded to 9,417 incoming telephone calls, covering a variety of subjects. The major topics are indicated in the chart shown below.

# **BOARD OFFICE TELEPHONE STATISTICS**



# COMPOUNDED DRUG TESTING REPORT

In 2003 the Board initiated a program to test drug preparations compounded by pharmacies. All preparations are tested for potency and, if applicable, sterility and endotoxin. The tables listed below are for the fiscal year ending June 30, 2007.

| Dosage Form            | Tests     |
|------------------------|-----------|
|                        | Performed |
| Capsule                | 37        |
| Injection              | 7         |
| I.V. solution          | 12        |
| Oral solution          | 2         |
| Oral suspension        | 140       |
| Suppository            | 5         |
| Tablet                 | 2         |
| Topical cream/ointment | 1         |
| Tramsdermal            | 6         |
| Troche                 | 1         |

| Test Results  | Tests<br>Performed | Percentage |
|---------------|--------------------|------------|
| Satisfactory  | 162                | 76.1%      |
| Unsatisfactor | 51                 | 23.9%      |
| у             |                    |            |
| Total         | 213                | 100%       |

All unsatisfactory results were related to potency failures. An acceptable potency range is considered +/- 10% of the expected potency, unless a U.S.P. monograph states a different range for a specific preparation. Failing potency results ranged from 21.2% to 450.4%. Pharmacies are notified of unsatisfactory results and asked to complete a quality assurance review of their compounding practices and provide a corrective action plan.

| Drugs with Unsatisfactory Results       |   |  |
|---|---|--|
| Azathioprine oral suspension            | Ketoprofen transdermal                            |  |
| Baclofen suppositories                  | Lansoprazole oral suspension                      |  |
| Biest/Progesterone capsules             | Metronidazole oral suspension                     |  |
| Biest/Progesterone/DHEA capsules        | Omeprazole oral suspension                        |  |
| Biest/Progestrone/Testosterone capsules | Piroxicam capsules                                |  |
| Boric Acid capsules                     | Progesterone capsules                             |  |
| Captopril oral suspension               | Progesterone suppositories                        |  |
| Carboplatin IV solution                 | Progesterone troches                              |  |
| Cisplatin IV solution                   | Progesterone/Melatonin/Hydroxytryptophan capsules |  |
| Clonidine injection                     | Rifampin oral suspension                          |  |
| DHEA capsults                           | Spironolactone/HCTZ oral suspension               |  |
| Diethylstilbestrol capsules             | Testosterone transdermal                          |  |
| Enalapril oral suspension               | Triest/DHEA capsules                              |  |
| Enalapril tablets                       | Triest/Progesterone capsules                      |  |
| Histamine Diphosphate injection         | Triest/Progesterone/DHEA/Testosterone capsules    |  |
| Histamine injection                     |   |  |



# COMPLAINTS FILED DISCIPLINE INFORMATION

# STATISTICS BELOW REFLECT TOTAL COMPLAINTS FOR THE FISCAL YEAR ENDING JUNE 30, 2007

Total Number of Complaints Received by the Board......415

| Breakdown of Complaint Allegations                    |    |  |
|---|----|--|
| Alcohol and Alcohol-Impaired Behavior                 | 6  |  |
| Audit Findings  | 41 |  |
| Billing for Services Not Rendered                     | 1  |  |
| Compounding   | 23 |  |
| Confidentiality                                       | 5  |  |
| Counseling  | 2  |  |
| Department of Revenue Tax Compliance                  | 11 |  |
| Dispensing Errors                                     | 46 |  |
| Drug Distribution Violations                          | 6  |  |
| Drugs and Drugs-Impaired Behavior                     | 27 |  |
| Errors/Improper/False Accounting Procedures           | 1  |  |
| Ethical   | 23 |  |
| Expired Drugs in Inventory                            | 1  |  |
| False/Misleading Advertising or Marketing             | 1  |  |
| Felony  | 5  |  |
| Fraud-Mail and Unspecified                            | 3  |  |
| Fraudulent Prescriptions                              | 9  |  |
| Improper Dispensing                                   | 20 |  |
| Incompetence  | 3  |  |
| Insurance Fraud-Non-government or Private Insurance   | 1  |  |
| Licensure Applicant                                   | 29 |  |
| Loss of Drugs   | 11 |  |
| No Jurisdiction                                       | 4  |  |
| Pharmacy Permit Violations (includes security issues) | 43 |  |
| Practicing Beyond the Scope of Practice               | 2  |  |
| Practicing without a License                          | 37 |  |
| Previous Disciplinary Action                          | 1  |  |
| Recordkeeping   | 5  |  |
| Substitution  | 1  |  |
| Theft of Drugs  | 27 |  |
| Theft of Drugs – Self-Administration                  | 2  |  |
| Theft of Money  | 4  |  |
| <b>Unauthorized Dispensing</b>                        | 2  |  |
| <b>Unprofessional Conduct</b>                         | 3  |  |
| Veterinary  | 2  |  |
| Violation of Disciplinary Order                       | 7  |  |

# SOURCE OF COMPLAINTS

| Complaints Received From Public              | 141 |
|--|-----|
| Complaints Received from Other Agencies      | 15  |
| Complaints Received from Board or Inspectors | 227 |
| Complaints Received from Other State Boards  | 5   |
| Complaints Regarding Licensing Issues        | 27  |

# DISPOSITION

|   | İ   |
|---|-----|
| Cases Referred to Legal Counsel                     | 51  |
|   |     |
| Cease and Desist Letters Sent                       | 3   |
| Disposition Complete – Other                        | 25  |
| Individuals Requested to Meet with the Board        | 40  |
| Investigations Requested/Not Complete               | 108 |
| The Congression of the Company                      |     |
| Letters of Concern Sent                             | 96  |
| Letters of Warning – Serious Violations Sent        | 60  |
| License Approved                                    | 1   |
| License Denied Letters                              | 6   |
| Miscellaneous Non-Administrative Board Letters Sent | 5   |
| No Action/Insufficient Evidence                     | 76  |
| Referred to Other Board/Agency                      | 10  |
| Technician Disqualification Letters Sent            | 59  |
| Technician Conditional Employment Letters Sent      | 31  |

# NOTE

Disposition numbers will not equal the number of complaints received and processed since some cases resulted in dual action; i.e., the pharmacist met with the Board and then received an administrative letter, or was referred to legal counsel for filing, etc.

# **DISCIPLINE**

| ACTIONS   |    |
|---|----|
| Complaints Filed with Administrative Hearing Commission | 17 |
| Disciplinary Hearings Held                              | 1  |
| Felony Hearings Held                                    | 3  |
| Violation of Discipline Hearings Held                   | 5  |
| Settlement Agreements Entered                           | 20 |
| Restricted Licenses Issued Pursuant to Section 620.149  | 9  |

| DISCIPLINE RESULTS  |   |
|---|---|
| Technician Registrations Suspended 324.010                              | 4 |
| Pharmacist Licenses Censured  | 1 |
| Pharmacist Licenses Revoked   | 3 |
| Pharmacy Permits Revoked  | 1 |
| Pharmacist Licenses Suspended Followed by Probation                     | 5 |
| Pharmacist Licenses on Probation  | 9 |
| Pharmacy Permits on Probation   | 3 |
| Drug Distributor Registrants on Probation                               | 1 |
| Drug Distributor Licenses on Probation                                  | 1 |
| Restricted Intern Licenses Issued Pursuant to Section 620.149           | 1 |
| Restricted Pharmacist Licenses Issued Pursuant to Section 620.149       | 3 |
| Restricted Pharmacy Permits Issued Pursuant to Section 620.149          | 1 |
| Restricted Drug Distributor Licenses Issued Pursuant to Section 620.149 | 4 |
| Pharmacist Licenses Voluntary Surrender                                 | 3 |
| Pharmacy Permits Voluntary Surrender                                    | 1 |

# NOTE

Since the time frame of cases from point of first review to the final disposition may be lengthy, the totals shown above will not necessarily balance. A case may be reviewed by Board, referred to legal counsel, filed with the Administrative Hearing Commission and be decided by disciplinary hearing, consent order or otherwise, all in separate fiscal years.

# CENSUS OF LICENSED PHARMACISTS AS OF JUNE 30, 2007

# TOTAL PHARMACISTS INSTATE AND OUT OF STATE

| <b>Total Licensed Pharmacists</b> | 7,782 |
|-----------------------------------|-------|
|                                   |       |
| Active license                    | 7,549 |
| Male                              | 4,036 |
| Female                            | 3,513 |
| Inactive license                  | 233   |
| Male                              | 130   |
| Female                            | 103   |
|                                   |       |

# TOTAL NUMBER OF PHARMACISTS RESIDING IN MISSOURI

| Active License – Practicing Pharmacy       | 4,875 |
|--|-------|
| Male                                       | 2,659 |
| Female                                     | 2,216 |
| Inactive License – Not Practicing Pharmacy | 63    |
| Male                                       | 41    |
| Female                                     | 22    |

# AGE GROUP BREAKDOWN OF INSTATE AND OUT-OF-STATE PHARMACISTS (AS OF JUNE 30, 2007)

| Under the age of 30 | 744   |
|---------------------|-------|
| Ages 30-39          | 2,012 |
| Ages 40-49          | 1,864 |
| Ages 50-59          | 1,947 |
| Ages 60-69          | 845   |
| Ages 70-79          | 315   |
| Ages 80-89          | 54    |
| Ages 90+            | 1     |









# CENSUS OF LICENSED PHARMACIES AS OF JUNE 30, 2007

| Total Licensed Pharmacies as of June 30, 2007 |       |
|---|-------|
| Instate Pharmacies                            | 1,380 |
| Non-Resident Pharmacies                       | 444   |
| Temporary Pharmacies                          | 6     |



# **BREAKDOWN OF INSTATE PHARMACIES BY CLASSIFICATION**

| Class A - Retail Pharmacies              | 482 |
|--|-----|
| Class B - Hospital Pharmacies            | 101 |
| Class C - LTC Pharmacies                 | 11  |
| Class D - Non-Sterile Compounding        | 0   |
| Class E - Radiopharmaceutical            | 11  |
| Class F - Renal Dialysis Pharmacies      | 1   |
| Class G - Medical Gas Pharmacies         | 0   |
| Class H - Sterile Products               | 2   |
| Class I - Consultant Pharmacy            | 2   |
| Class J - Shared Services Pharmacy       | 2   |
| Pharmacies with Multiple Classifications | 768 |

# CENSUS OF DRUG DISTRIBUTORS/MANUFACTURERS LICENSED AS OF JUNE 30, 2007

| Drug Distributors Licensed with a Permanent License | 1,235 |
|---|-------|
| Drug Distributors Licensed with a Temporary License | . 14  |
| Out-of-State Manufacturers Registered               | . 101 |



# **NOTE**

Any out-of-state drug company or manufacturer that ships/transfers legend drugs or devices into this state is required to obtain an out-of-state drug distributor license with this office.

Upon receipt of a license application, the company is issued a temporary license. This temporary license is valid for a period of one (1) year or until the application has been completely processed by this office, at which time, a permanent license is issued or the application is denied by the Board.

All in-state drug companies that ship/transfer legend pharmaceuticals are also required to obtain licensure with this office.

Any pharmacy that distributes legend drugs to any entity other than the consumer (the patient), such as other pharmacies, physicians, etc., must obtain a drug distributor's license if that type of distribution exceeds 5% of the pharmacy's total gross sales of legend products.

# **CENSUS OF OTHER LICENSEES AS OF JUNE 30, 2007**

| Licensed Interns                |        |
|---------------------------------|--------|
| Registered Pharmacy Technicians | 14,735 |

# MISSOURI BOARD OF PHARMACY INSPECTORS AND COUNTIES ASSIGNED

| #1 VanFleet | #2 Heavin | #3 Glenski | #4 Kidd                | #5 Wood                       | #6 Alexander                  | #7 Werges |
|-------------|-----------|------------|------------------------|-------------------------------|-------------------------------|-----------|
|             |           |            |                        |                               |                               |           |
| Barton      | Barry     | Andrew     | Butler                 | Bollinger                     | Adair                         | Audrain   |
| Bates       | Christian | Atchison   | Carter                 | Cape Girardeau                | Clark                         | Benton    |
| Cass        | Dade      | Buchanan   | Iron                   | Dunklin                       | Knox                          | Boone     |
| Cedar       | Dallas    | Caldwell   | Jefferson              | Franklin                      | Lewis                         | Callaway  |
| Henry       | Douglas   | Carroll    | Madison                | Mississippi                   | Lincoln                       | Camden    |
| Jackson     | Greene    | Clay       | Reynolds               | New Madrid                    | Marion                        | Chariton  |
| Johnson     | Howell    | Clinton    | Ripley                 | Pemiscot                      | Monroe                        | Cole      |
| St. Clair   | Jasper    | Davies     | Shannon                | Perry                         | Montgomery                    | Cooper    |
| Vernon      | Lawrence  | Dekalb     | St. Francois           | Scott                         | Pike                          | Crawford  |
|             | McDonald  | Gentry     | STL City               | St. Charles                   | Ralls                         | Dent      |
|             | Newton    | Grundy     | STL County             | Ste. Genevieve                | Schuyler                      | Gasconade |
|             | Oregon    | Harrison   | Washington             | STL City                      | Scotland                      | Hickory   |
|             | Ozark     | Holt       | Wayne                  | STL County                    | Shelby                        | Howard    |
|             | Polk      | Lafayette  |                        | Stoddard                      | STL City                      | Laclede   |
|             | Stone     | Linn       |                        |                               | STL County                    | Macon     |
|             | Taney     | Livingston |                        |                               | Warren                        | Maries    |
|             | Texas     | Mercer     |                        |                               |                               | Miller    |
|             | Webster   | Nodaway    |                        |                               |                               | Moniteau  |
|             | Wright    | Platte     |                        |                               |                               | Morgan    |
|             |           | Putnam     |                        |                               |                               | Osage     |
|             |           | Ray        |                        |                               |                               | Pettis    |
|             |           | Sullivan   |                        |                               |                               | Phelps    |
|             |           | Worth      | Pharmacies in          | Drug                          | Pharmacies &                  | Pulaski   |
|             |           |            | St. Louis City         | Distributors                  | Drug Distributors             | Randolph  |
|             |           |            | & County South of Hwy. | in St. Louis<br>City & County | in St. Louis City<br>& County | Saline    |
|             |           |            | 40                     | South of Hwy.                 | North of Hwy. 40              |           |
|             |           |            |                        |                               |                               |           |